

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

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IN RE: ZIMMER NEXGEN KNEE )	MDL No. 2272
IMPLANT PRODUCTS LIABILITY) )	
LITIGATION )	Master Docket Case No. 11 C 05468
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This Document Relates to All Cases )	Judge Rebecca R. Pallmeyer

**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR  
LEAVE TO FILE WRITTEN POSITION STATEMENTS AND  
FOR PRESENTATION OF POSITIONS IN COURT**

NOW COMES, Plaintiffs' Lead and Liaison Counsel and for their Response to Defendants' Motion for Leave to file Written Position Statements and for Presentation of Positions in Court states:

**PRELIMINARY STATEMENT**

At the first status conference held before this Court on September 16, 2011, Plaintiffs proposed the use of position statements to outline the parties' respective positions, provided the statements were limited in size and scope. Since that time, however, through both briefing and argument at the recent October 7, 2011 status conference, the parties have educated the Court on some of the basic issues associated with the case. While "position papers" can serve a useful purpose to educate the Court, they should not be employed as an advocacy piece to color the views of the Court, before any meaningful discovery has been supplied. But that is what Defendants are seeking. Other than such advocacy, little will be gained from submission of additional "position papers" at this time. As set forth in Plaintiffs' motion to compel more complete Rule 26 disclosures, Defendants have thus far failed to produce documents or information that would enable Plaintiffs to reasonably expand upon that which has already been provided to the Court. As a result, Plaintiffs will be substantially disadvantaged. If the Court so Orders additional position papers, plaintiffs will comply but would respectfully request that such position papers not be submitted until Defendants have: 1) substantially satisfied their disclosure obligations pursuant to Fed. R. Civ. P. 26; 2) provided substantive responses to Plaintiffs'

outstanding discovery requests; and 3) produced witnesses pursuant to Plaintiffs' initial 30(b)(6) deposition notices.

The Plaintiffs' Steering Committee respectfully requests the Court deny the Zimmer Defendants' motion at this time and in support thereof respectfully state as follows:

1. At the first status conference on September 16, 2011, plaintiffs' co-lead counsel, James Ronca, suggested that the parties submit briefing or position statements outlining the litigation. Transcript of September 16, 2011, Proceedings – Rule 16 Conference Before the Honorable Rebecca R. Pallmeyer at 28.
2. The Court agreed with the suggestion of the plaintiffs' lead counsel, and further suggested that a demonstration or PowerPoint on the scientific or medical issues presented by MDL 2272 would be useful. *Id.* at 28-29.
3. The Zimmer Defendants also agreed with the plaintiffs' suggestion regarding position papers and presentations. The Court then asked the parties to work together to schedule the presentations. *Id.* at 30-31.
4. On September 27, 2011, lead counsel for the parties conducted a teleconference on a variety of issues, including scheduling of the submission of position statements and presentations to the Court. Although Plaintiffs proposed that position papers be submitted prior to and presented to the Court at the October 7, 2011 status conference, Defendants objected to that schedule. The parties also discussed “ground rules” for the position papers which would have included (1) page limitations, (2) simultaneous filing, (3) prohibitions against referencing anything other than publically available documents, and (4) efforts to limit advocacy in the position papers. The parties did not reach agreement on the presentment of position papers.
5. Because the parties were unable to agree upon “ground rules” or timing related to the submission of position papers, Plaintiffs' counsel did not prepare any such presentation.

6. The Court conducted its second status conference on October 7, 2011. Although no position presentations were scheduled for that conference, the parties submitted extensive briefing in connection with the privilege and protective order issues that covered, for the most part, all of the issues that would have been raised in the position papers. In fact, Zimmer filed a 15-page brief on the protective order issue that included the following:

- The basics of Total Knee Replacement Surgery and the Zimmer Entities NexGen knee replacement Products;
- Anatomical diagrams;
- Discussions relating to the alleged differences between the designs of various femoral components;
- A critique of Plaintiffs' use of the data and conclusions from the Berger-Della Valle presentation at the American Academy of Orthopedic Surgeons in March 2010;
- A critique on Plaintiffs' use of the Zimmer 510(k) applications relating to the various Zimmer products at issue;
- A 27-page "design rationale" document for the NexGen Flex line, consisting of internal information supporting the design of the product line;
- An affidavit from Paul Daniel, a Zimmer employee, attesting that both Drs. Berger and Della Valle still use Zimmer NexGen Flex femoral components; and
- Reference to the affidavit by of Michelle Zawadzki, a Zimmer employee, about the alleged differences in the various components in the NexGen Product line.

At the status conference, both parties were provided equal time to address the principle issues and outline their respective positions.<sup>1</sup> In short, both parties presented their positions in detail, Zimmer even using posters to show alleged differences in the implants and exemplars at the podium for purposes of demonstration.

7. After the October 7, 2011 status conference, considering the detail already provided to the court, on October 14, 2011, Plaintiffs' counsel explained to Defendants that no additional position statements seemed necessary.

8. The parties again conferred by telephone on October 25, 2011, and Mr. Ronca

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<sup>1</sup> While exact times can not be measured, a review of the applicable transcript demonstrates that both sides were given equal opportunity (Plaintiffs' dialogue consists of 33 pages of transcript, Zimmer 34).

reaffirmed Plaintiffs' position that no additional position statements or presentations would be necessary at this time.

9. While the Manual On Complex Litigation, 4<sup>th</sup>, Rule 11.11 (2004) mentions the possibility of position statements as one of many items that might be covered during the early stages of MDL mass tort litigation, it actually states:

Also worth considering are the following:

- \* \* \*
- directing counsel to submit a tentative statement, joint if possible, identifying disputed issues as specifically as possible;
- \* \* \*
- calling on counsel to submit brief factual statements to assist the court in understanding the background, setting, and likely dimensions of the litigation;

It is Plaintiffs' position that the above has already been accomplished and does not need to be repeated.

10. Plaintiffs' counsel do not dispute that this MDL involves complex engineering and medical issues regarding the design, manufacture, implantation, and use of multiple artificial knee components. However, at this early juncture, presentations beyond that which has already been provided to the Court will serve little purpose except to substantially prejudice the plaintiffs.

11. Importantly, as it relates to presenting more detailed positions, to date, Zimmer has not yet produced documents, 30(b)(6) witnesses, or even substantive Rule 26 disclosures. Until such as time as discovery progresses, Plaintiffs ability to present more than what has previously been presented to the Court is limited. In contrast, Zimmer is in a position to "pick-and-choose" what will be presented to the Court because Zimmer possesses all of the information, both good and bad, about their products, their people, and their position. By way of simple example, while Zimmer has previously offered an affidavit to the Court suggesting that Drs. Berger and Della Valle continue to use NexGen Flex femoral components, the affidavit is silent and Plaintiffs do not currently have the ability to challenge issues relevant to said affidavit such as:

- The specific types of femoral components being used;
- The mode of fixation – cemented, uncemented, both;
- The criteria being used for patient selection and recommendation of Flex devices;
- Whether the number of Flex devices being used has increased or decreased;
- Why Dr. Berger, a consulting surgeon who personally received over \$5 million from Zimmer in 2008 and who Defendants contend continues to use NexGen Flex femoral components, offered a study to the American Academy of Orthopedics in 2010 which states “[t]his component is still commercially available but should not be used for any patient.” (emphasis added);<sup>2</sup> and
- Whether (and if so how much) both Drs. Berger and Della Valle continue to receive compensation from Zimmer.

By way of further example, although Zimmer submitted a 2004 “design rationale” to the Court for purposes of the October 7 status conference, the “design rationale” is based upon information that, at minimum, is eight years old.<sup>3</sup> The “design rationale” begs the following questions which could not be answered by anyone except Defendants at this stage:

- What data, if any, has developed in the succeeding 7 years that would be relevant to the “design rationale”?
- Did Zimmer, at any time, revisit the “design rationale” so that it could be updated?
- If so, how many times?
- Has Zimmer considered any clinical data or adverse event reporting in assessing the 7 year old “design rationale”?

There is rarely a circumstance in American jurisprudence where a litigant is not afforded the right to confront witnesses offered in opposition to them. Position papers here, beyond what the Court has already heard, would serve little purpose. Zimmer’s real purpose in moving for leave to file position statements is reflected in their motion at paragraph 10.

Zimmer contends that the overwhelming scientific evidence, and the documented high success rates of these products in the hands of thousands of doctors around the world, rebut the plaintiffs’ claims of defect. Presentation of the parties’

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<sup>2</sup> The presentation, entitled “The High Failure Rate of a High-Flex Total Knee Arthroplasty Design,” reported on the cementless NexGen CR Flex femoral component. <http://www3.aaos.org/education/anmeet/anmt2010/podium/podium.cfm?Pevent=434>

<sup>3</sup> The most recently published article cited in the “design rationale” is from 2003. Further, the document purports to be based upon information “on file at Zimmer” and, therefore, currently unknown to anyone but Zimmer.

positions on these issues to the Court relatively early in this proceeding may aid the Court at an important juncture in this MDL.

While scientific evidence and “documented high success rates” may ultimately serve Defendants’ purpose in defending against liability, such information should not be unilaterally offered to the Court under the guise of “position papers” to ultimately serve as a mini-summary judgment mechanism.

WHEREFORE, Plaintiffs’ respectfully requests the Court deny Zimmer’s motion or, in the alternative, schedule any such presentation after substantive discovery in this matter has occurred.

Dated: November 4, 2011

RESPECTFULLY SUBMITTED,

/s/ Peter J. Flowers

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***ATTORNEYS FOR PLAINTIFFS***

**CERTIFICATE OF SERVICE**

I hereby certify that on November 4, 2011, I electronically filed the foregoing document with the clerk of the court for the U.S. District Court, Northern District of Illinois, using the electronic case filing system of the Court.

/s/ Peter J. Flowers\_\_\_\_\_